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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,668	10/06/2003	Helene G. Bazin	006401.00415	4079
22908	7590	03/20/2006	EXAMINER	
BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606			PRATS, FRANCISCO CHANDLER	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,668

Applicant(s)

BAZIN ET AL.

Examiner

Francisco C. Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-20-05</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-33 are pending and are examined on the merits.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that

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was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 and 12 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Whistler (U.S. Pat. 4,985,082).

The reference discloses products which appear to be identical to the presently claimed products, based on the fact that the same starting material as claimed, granular starch, is contacted with the same enzyme as claimed, glucoamylase from *Aspergillus niger*, under the same non-gelatinizing conditions as claimed, so as to produce glucoamylase-hydrolyzed granular starch having the ability to adsorb hydrophobic substances. See Whistler at column 4, lines 5-43 (Example 1), including the disclosure of incorporating the hydrolyzed starch in a "body cream," which is clearly a cosmetic product as recited in claim 12, as well as the suitability of cross-linked starch in the disclosed applications. Note further the suitability of using glucoamylase from *A. niger* (column 2, lines 4-6). Consequently, the claimed products appear to be anticipated by the reference.

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It is noted the reference does not explicitly disclose the use of acidification to stop the enzyme reaction, as recited in the process limitations of these rejected product-by-process claims. However, even if the reference products and the claimed product are not one and the same and there is, in fact, no anticipation, the reference products would, nevertheless, have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made, in view of the fact that any nominal change in the properties of the starch would have been the change reasonably expected from using acidification to stop the enzyme reaction. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 11-14 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kobayashi et al (U.S. Pat. 5,445,950).

The reference discloses products which appear to be identical to the presently claimed products, based on the fact that the same starting material as claimed, granular starch, is contacted with the same enzyme as claimed, glucoamylase, under the same non-gelatinizing conditions as claimed, so as to

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produce glucoamylase-hydrolyzed granular starch having the ability to adsorb hydrophobic substances. See Kobayashi at column 3, lines 45-68 (Table 1), as well as the discussion at column 11, lines 14-24, regarding the hydrophobic adsorptive properties of the enzymatically hydrolyzed product. Note that the water in Kobayashi's product can be considered a "skin contacting ingredient" as recited in claim 12. Consequently, the claimed products appear to be anticipated by the reference.

It is noted that the reference does not explicitly disclose the use of acidification to stop the enzyme reaction, as recited in the process limitations of these rejected product-by-process claims. However, even if the reference products and the claimed product are not one and the same and there is, in fact, no anticipation, the reference products would, nevertheless, have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made, in view of the fact that any nominal change in the properties of the starch would have been the change reasonably expected from using acidification to stop the enzyme reaction. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

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Lastly, with respect to the propriety of this type of "alternative" rejection, note again that MPEP § 2113 states that:

. . . [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP § 2113 also clearly states that

'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974).

Claim Rejections - 35 USC § 103

Claims 1-4, 6-10 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whistler (U.S. Pat. 4,985,082) in view of Aggarwal (Thermochimica Acta 319:17-25 (1998)).

As discussed above, Whistler discloses the production of porous starch granules by contacting the starch granules below the gelatinization temperature with glucoamylase from the claimed microorganism, thereby partially hydrolyzing the granules. Whistler differs from the claims in that Whistler

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does explicitly disclose the use of lowering the pH or acidifying the hydrolysis milieu to stop the enzymatic reaction. However, the use of acidification is extremely well known in the art of enzymatic hydrolyses as a suitable method for stopping reactions at a desired time. In fact, Aggarwal discloses that acidification is suitable for stopping the action of glucoamylase on starch granules, so as to produce porous starch granules, the precise enzymatic reaction carried out by Whistler. See page 18, right hand column, first paragraph. Aggarwal cannot be considered anticipatory of the claims under examination, in view of the fact that it is not clear what degree of hydrolysis is employed, and therefore whether the degree of hydrolysis necessarily or inherently results in a granule which is hydrophobic. However, Aggarwal clearly suggests to the artisan of ordinary skill that acidification is a suitable means of stopping the action of glucoamylase on starch granules. Recognizing from Aggarwal the suitability of acidification for stopping the action of glucoamylase on starch granules, the artisan of ordinary skill would have been motivated to have used this method in the processes disclosed by Whistler.

Whistler does not use the starch concentration recited in claim 7 or the enzyme concentration recited in claim 8.

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However, the selection of a specific substrate concentration and/or concentration of enzyme suitable for use in an enzymatic process such as Whistler's was clearly a matter of routine optimization on the part of the artisan of ordinary skill at the time of applicant's invention, and therefore clearly obvious under § 103(a). Further still, the use of a grinding step clearly would have been useful in determining mechanical properties of the granules, as well as in the creation of fine powders of the starch granules disclosed in Whistler. A holding of obviousness over the cited references is therefore clearly required.

Claims 1-9, 15-20, 22-29 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al (U.S. Pat. 5,445,950) in view of Aggarwal (Thermochimica Acta 319:17-25 (1998)).

As discussed above, Kobayashi discloses the production of porous starch granules by contacting the starch granules below the gelatinization temperature with glucoamylase, α -amylase, or a combination thereof, and thereby partially hydrolyzing the granules. Note in particular Kobayashi's hydrolysis to decompositions levels of less than 1% (see, e.g., abstract), as well as the use of 25% starch in the hydrolysis medium using

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glucoamylase. See column 3, lines 64-67, using 25 grams of starch per 100 ml of buffer. Kobayashi differs from the claims in that Kobayashi does explicitly disclose the use of lowering the pH or acidifying the hydrolysis milieu to stop the enzymatic reaction. However, as discussed above, the use of acidification is extremely well known in the art of enzymatic hydrolyses as a suitable method for stopping reactions at a desired time. As also discussed above, Aggarwal discloses that acidification is suitable for stopping the action of glucoamylase on starch granules, so as to produce porous starch granules, the precise enzymatic reaction carried out by Whistler. As also discussed above, Aggarwal cannot be considered anticipatory of the claims under examination, in view of the fact that it is not clear what degree of hydrolysis is employed, and therefore whether the degree of hydrolysis necessarily or inherently results in a granule which is hydrophobic. However, Aggarwal clearly suggests to the artisan of ordinary skill that acidification is a suitable means of stopping the action of glucoamylase on starch granules. Recognizing from Aggarwal the suitability of acidification for stopping the action of glucoamylase on starch granules, the artisan of ordinary skill would have been motivated to have used this method in the processes disclosed by Kobayashi.

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Kobayashi does not use the enzyme concentration recited in claim 8. However, the selection of a specific concentration of enzyme suitable for use in an enzymatic process such as Kobayashi's was clearly a matter of routine optimization on the part of the artisan of ordinary skill at the time of applicant's invention, and therefore clearly obvious under § 103(a). Further still, the use of a grinding step clearly would have been useful in determining mechanical properties of the granules, as well as in the creation of fine powders of the starch granules disclosed in Kobayashi. Lastly, the use of glucoamylase from a well-known source, such as *A. niger*, as recited in claims 31-33, must be considered obvious absent some demonstration of an unexpected resulting stemming from obtaining the enzyme from that organism. A holding of obviousness over the cited references is therefore clearly required.

Claims 1-10 and 15-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al (U.S. Pat. 5,445,950) in view of Aggarwal (Thermochimica Acta 319:17-25 (1998)), as applied to claims 1-9, 15-20, 22-29 and 31-33 above, and in further view of Whistler (U.S. Pat. 4,985,082).

As discussed above, Kobayashi, when taken in view of Aggarwal, renders obvious the claimed process of digesting

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starch with glucoamylase to produce granules having the claimed degree of hydrolysis, followed by pH denaturation of the enzyme. However, neither Kobayashi nor Aggarwal suggests the claimed process of digestion wherein cross-linked starch is digested to the claimed degree of hydrolysis of less than 5%, or less than 1%, as recited in new claims 21 and 30. However, Whistler clearly discloses that using cross-linked starch granules imparts improved structural strength in the product which results from partial enzymatic hydrolysis. See column 2, lines 28-35. Thus, the artisan of ordinary skill, recognizing from Whistler the advantages of using cross-linked starch, clearly would have been motivated to have used cross-linked starch in the processes disclosed by Kobayashi. A holding of obviousness is therefore required.

No claims are allowed.

This is a continuation of applicant's earlier Application No. 09/961,867. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first

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action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

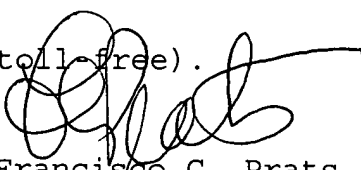
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can

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be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP